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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 10/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,138	DYER, WALLACE K.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,7-11,13,22,23,25-29 and 31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,7-11,13,22,23,25-29 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/22/06 has been entered. Claims 1.4.7-1 1.13 and 20-30 were pending. Claims 1 and 22 were amended. Claims 20, 21, 24 and 30 were cancelled and claim 31 was added. Therefore, claims 1, 4, 7-11, 13, 22, 23, 25-29 and 31 are pending.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

Priority

2. Applicants' claim for domestic priority under 35 U.S.C. § 119(e) is acknowledged. However, Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 119(e) as follows:

This application claims the benefit of 60/229,085 filed 08/30/2000 (referred to herein as '085), and claims benefit of 60/229,989 filed 09/05/2000 (referred to herein as '989), and claims benefit of 60/241,636 filed 10/19/2000 (referred to herein as '636). However, the '085, '989, and '636 applications fail to provide adequate support under 35 U.S.C. § 112, first paragraph for the claimed invention as follows:

(A) For ***claims 1, 4, 7-11, 13, 22, 23, 25-29 and 31***, the '085, '989, and '636 applications fail to provide support for the currently claimed "high density" polyethylene or the "upper limits" in the "greater than" 60 or 100 micron particle range (e.g., see New Matter rejections below, which are incorporated in their entireties herein by reference).
(B) For ***claims 4***, the '085, '989 applications fail to provide support for the "saline" embodiment.

If applicant believes this assessment is in error, applicant must disclose where in the specification support for these limitations can be found. See MPEP § 714.02. Therefore the filing date of the instant application is deemed to be its actual filing date, **August 30, 2001**.

Withdrawn Objections/Rejections

3. The Bison rejection under 35 U.S.C. § 102 is withdrawn in part (i.e., with respect to claim 22 and its dependent claims) in view of Applicants' amendments that incorporated the limitations of claim 24 into claim 22. All other rejections are maintained and the arguments are addressed below.

Outstanding Objections and/or Rejections

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4, 7 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bisson (FR 2785811) (Publication date is **May 19, 2000**) (of record). Please note that priority was not afforded to the provisional applications (see above).

For ***claims 1, 4, 7 and 13***, Bisson (see entire document) discloses compositions comprising porous microparticles and/or a suspension agent used for soft tissue augmentation (e.g., see Bisson translation, page 1, paragraph 1; see also claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"), which anticipates the claimed invention. For example, Bisson discloses biocompatible micronized textured polyethylene particles with a size greater than 60 microns (e.g., see Bisson translation, page 4, paragraphs 1-2, "The material which constitutes the microparticles will be ... polyethylene"; see also claim 3, "Composition ... characterized in that the particles have a spherical or ovoid shape with a diameter greater than approximately 10 μm, preferably 30-100 μm [i.e., these are "micronized" particles]"). In addition, Bisson discloses a "textured" microparticles (e.g., see Bisson translation, claim 1, "Composition comprising porous microparticles [i.e., has a "textured" surface] whose pore diameter excludes the penetration of figured elements having a molecular weight of more than 1000 kilodaltons"). Bisson also discloses "high density" polyethylene (e.g., see page 3, "For example, one can use a polymer chosen from ... polyethylene, preferably 'high density'"). Finally, Bisson discloses a physiological carrier (e.g., Bisson translation, claim 1, "composition comprising porous microparticles ... a biocompatible suspension agent [i.e., a physiological carrier]"; see also page 5, see also claim 12, "Composition according to any one of Claims 8-10, characterized in that the suspension agent is a liquid or a gel chosen from the polymers of substituted or unsubstituted acrylamide, of vinylpyrrolidone, of hydroxyalkyl acrylate, or the copolymers of substituted or unsubstituted acrylamide and of another molecule

bearing a positive electric charge, such as a quaternary ammonium cationic monomer"). The examiner also notes that the above composition is used for "soft tissue augmentation" and is explicitly injected into soft tissue (e.g., see page 1, paragraph 1, "The present invention concerns compositions comprising porous microparticles and/or a suspension agent ... usable for implantation in a tissue, in particular to increase the volume of this tissue ("soft tissue augmentation"), notably in view of correcting in a lasting manner a deficit in the appearance or the function of this tissue or organ").

Response

5. Applicant's arguments directed to the above 35 U.S.C. § 102 rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

[1] Applicants argue, "Claim 1 has been amended to recite biocompatible micronized high density polyethylene particles having a size greater than one-hundred microns ... Bisson's particles are less than one-hundred microns ... Bisson teaches away from using particles with diameters greater than 100 microns ... which recites the disadvantages of using particles with diameters more than 100 microns as they risk giving the tissue a "visually perceivable roughness") ... Bisson further teaches away from using particles with diameters more than 100 microns in this paragraph by stating that it would be more difficult to inject the product through a needle" (e.g., see 8/22/06 Response, pages 5 and 6).

[2] Applicants argue, "Claim 22 has been amended to include limitations found in claim 24, namely the K values of polyvinylpyrrolidone. Claim 24 was not rejected in view of Bisson. Accordingly, amended Claim 22 is novel over Bisson and Applicant requests withdrawal of the rejection of Claim 22 and its dependent claims" (e.g., see 8/22/06 Response, page , paragraph)"

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. Bisson merely teach that "greater than" 100 microns is a "less preferred" embodiment (e.g., see "The microparticles which are used in the composition according to the invention preferably have a spherical or ovoid form, and a diameter of more than approximately 10 μm [i.e., which would explicitly include >100 μm], in particular a diameter of 30-100 pm, preferably 30-60 pm [i.e., the small ranges are just "preferred" embodiments]"). Therefore, Bisson teaches all of the claimed limitations. In addition, it is well settled that non-preferred embodiments constitute prior art (e.g., see MPEP § 2123, "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989)"). For example, Bisson does not state that larger particles are "impossible" to inject particles with greater than 100 microns, only "difficult", which constitutes a "less preferred" embodiment. Furthermore, "teaching away" arguments are not applicable to 35 U.S.C. § 102 rejections. In addition, Applicants use of the term "size" is indefinite (e.g., see 35 U.S.C. 112, second paragraph rejection below) and, as a result, Applicants' arguments are moot because the metes and bound of the claimed invention cannot be determined.

[2] The Examiner finds this argument persuasive and, as a result, the rejection is

withdrawn with respect to claim 22 and its dependent claims.

Accordingly, the 35 U.S.C. § 102(b) rejection cited above is hereby maintained.

Claims Rejections - 35 U.S.C. 112, first paragraph

6. Claims 1, 4, 7-11, 13, 22, 23, 25-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

Claims 1, 13, 22, 23, 28, 29 and 31 recite the limitation "high-density" polyethylene. However, the Examiner cannot find support for this genus. Specifically, the specification only recites one species of processed high-density polyethylene i.e., solid MEDPOR (e.g., see specification, paragraphs 30, 43 and 58), not all forms of processed polyethylene as currently claimed. For example, in *In re Grimme, Keil, and Schmitz* 124 USPQ 499 (CCPA 1960) the Court held that naming one member of a chemical genus (i.e., a single species) is not, in itself, proper basis for a claim to an entire chemical genus unless the genus is sufficiently identified in the application by other appropriate language (e.g., see *In re Grimme, Keil and Schmitz* 124 USPQ 499, 501) ("On the other hand, in the case of a small and closely related group such as the halogens, the naming of the group should ordinarily be sufficient since nothing of consequence would be added by also naming each of the well known members of the group"). Here, Applicants failed to "name the group" and thus do not provide any "identifying" language (i.e., the specification does not recite the use of a "high density polyethylene"

genus) that would support the claimed genus. Therefore, the disclosure of a single species (i.e., solid MEDPORE) fails to satisfy the test set forth in *In re Grimme, Keil and Schmitz* because Applicants have not provided any "identifying" language and, as mentioned above, a single species is not, in itself, a proper basis for a claim to an entire chemical genus unless such identifying language is set forth in the specification.

Response

7. Applicant's arguments directed to the above New Matter rejection were fully considered (and are incorporated in their entirety herein by reference) but were not deemed persuasive for the following reasons. Please note that the above rejection has been modified from it original version to more clearly address applicants' newly amended and/or added claims and/or arguments.

Applicants argue that high-density polyethylene is not a "genus" as purported (e.g., see 8/22/06 Response, page 7, paragraph, "Tupperware, milk cartons or any other forms of HDPE products are not different species of the genus "high-density" polyethylene") and, as a result, the description of MEDPORE, which has been used "interchangeably" with high-density polyethylene should suffice to prove Applicants' were in possession of the claimed invention (e.g., see 8/22/06 Response, page 7, paragraph 1, "[the] Declaration of Dr. Robert D. Wallace ... indicate[s] ... the terms MEDPOR and high density polyethylene have been used interchangeably"). In further support of this position Applicants also refer to Exhibits B-D and Dr. Perkins filed January 6, 2006 (e.g., see 8/22/06 Response, pages 6-9, see also exhibits; see also 8/22/06 Declaration; see also).

This is not found persuasive for the following reasons:

The Examiner respectfully disagrees. The declarations under 37 CFR 1.132 and exhibits filed 8/22/06, 6/27/06 and 1/31/06 are insufficient to overcome the rejections of claim 1, 4, 7-11, 13, 22, 23, 25-29 and 31 based upon 35 U.S.C. § 112, first paragraph as set forth in the last Office action because:

The general test for determining whether later claimed subject matter is supported by an earlier written description is whether the disclosure of the application "reasonably conveys to a person skilled in the art that the inventor had possession of the claimed subject matter at the time of the earlier filing date." *Eiselstein v. Frank*, 52 F.3d 1035, 1039, 34 USPQ2d 1467, 1470 (Fed. Cir. 1995); *Ralston Purina Co. v. Far-Mar-Co., Inc*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985). The specification must provide information that clearly allows persons having ordinary skill in the art to recognize that the applicant invented the later claimed subject matter. In re *Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989).

The Federal Circuit has analogized the determination of whether there is written descriptive support in a specification to following a trail through the forest by looking for "blaze marks" on individual trees:

> Many years ago our predecessor court graphically articulated this standard by analogizing a genus and its constituent species to a forest and its trees. As the court explained:
>
> > It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees.

Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996), quoting *In re Ruschig*, 379 F.2d 990, 994-95, 154 USPQ 118, 122 (CCPA 1967). "Precisely how close the original description must come to comply with the description requirement of Section 112 must be determined on a case-by-case basis." *Eiselstein*, 52 F.3d at 1039, 34 USPQ2d at 1470,

quoting *Vas-Cath*, 935 F.2d at 1561, 19 USPQ2d at 1116, quoting *In re Smith*, 481 F.2d 910, 914, 178 USPQ 620, 623-24 (CCPA 1973).

The determination that newly added subject matter meets § 112's written description generally involves at least one of three factors. The first involves the situation where claimed language is literally stated in the specification, (i.e., literal antecedence in the specification for the newly added subject matter). The description requirement is ordinarily met by a specification that describes the invention in the same words as the claims. *In re Bowen*, 492 F.2d 859, 864, 181 USPQ 48, 52 46 (CCPA 1974). See also, *Snitzer v. Etzel*, 465 F.2d 899, 902, 175 USPQ 108, 110-11 (CCPA 1972), appeal after remand, 531 F.2d 1062, 189 USPQ 415 (CCPA 1976); *Martin v. Johnson*, 454 F.2d 746, 751-52, 172 USPQ 391, 395 (CCPA 1972). Here, it is undisputed that Applicants have failed to provide literal support for the term "high-density polyethylene" as currently claimed.

If the new limitation is not literally set forth, then it must next be determined whether the limitation was actually described although in different language. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984) ("It is not necessary that the claimed subject matter be described identically . . . ."); *In re Lukach*, 442 F.2d 967, 968-69, 169 USPQ 795, 796 (CCPA 1971). (The written description requirement does not require in haec verba antecedence in the originally filed application). However, where different language is relied upon for support, "the specification must contain an equivalent description of the claimed subject matter." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); Wagoner v. Barger, 463 F.2d 1377, 1380, 175 USPQ 85, 86 (CCPA 1972). Here, contrary to Applicants' assertion, the word MEDPORE and "high-density polyethylene" are not equivalent.

Although, MEDPORE may contain high-density polyethylene, it is clear from the record (and Applicants' own admissions) that MEDPORE represents but one "species" of materials that uses high-density polyethylene. For example, it is undisputed that both "porous" and "non-porous" polyethylene exists. Although both of these materials each contain high-density polyethylene, they are not "equivalent" because one contains larger pores than the other. Thus, they are structurally distinct. Furthermore, none of Applicants' 132 declarations allege that MEDPORE can be used "interchangeably" with non-porous high-density polyethylene. The 8/22/06 declaration by Dr. Wallace only states, "MEDPOR and high density polyethylene have been used interchangeably" (e.g., see 8/22/06 Wallace Declaration, page 1, paragraph 3), which does not equate to the same thing. That is, Dr. Wallace never states MEDPOR is non-porous.

Likewise, other forms of polyethylene are also structurally distinct as alluded to previously (e.g., see 4/27/06 final rejection, paragraph bridging pages 9 and 10). Whether this difference is the result of a "processing" parameter is not material. In addition, Applicants' admit that non-sterilized forms would not be used in surgery (e.g., see If the HDPE containing article is intended to be used as a container, it will be made in a suitable shape and will not be sterilized"). Therefore, Applicants have clearly admitted on the record that they are not in possession of all "processed" forms of high-density polyethylene to which their claims are currently drawn.

Last, if neither explicit language nor equivalent language is present, then it must be determined if the newly claimed feature is inherently present in the specification. *Therma-Tru Corp. v. Peachtree Doors Inc.*, 44 F.3d 988, 993, 33 USPQ2d 1274, 1276 (Fed. Cir. 1995) ("[T]he later explicit description of an inherent property does not deprive the product of the

benefit of the filing date of the earlier application."). Proof of inherency requires evidence that the "necessary and only reasonable construction to be given the disclosure by one skilled in the art is one which will lend clear support to . . . [this] positive limitation. . . ." *Kennecott Corp. v. Kyocera International Inc.*, 835 F.2d 1419, 1423, 5 USPQ2d 1194, 1198 (Fed. Cir. 1987) quoting *Langer v. Kaufman* , 465 F.2d 915, 918, 175 USPQ 172, 174 (CCPA 1972) quoting *Binstead v. Littmann* , 242 F.2d 766, 770, 113 USPQ 279, 282 (CCPA 1957). In *Kennecott*, 835 F.2d at 1423, 5 USPQ2d at 1198, the court noted:

> The court has generally applied this standard of the "necessary and only reasonable construction" as a basis for determining whether an application could, on the basis of an inherent property, support a limitation in an interference count. [Citations omitted.]

As noted by the CCPA:

> Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [Citations omitted.] If, however, the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient.

In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981), quoting, *Hansgirg v. Kemmer*, 102 F.2d 212, 214, 40 USPQ 665, 667 (CCPA 1939). Thus, it is not sufficient that a person following the disclosure might obtain the result set forth; it must inevitably happen. *Dreyfus v. Sternau*, 357 F.2d 411, 415, 149 USPQ 63, 66 (CCPA 1966); Crome v. Morrogh, 239 F.2d 390, 392, 112 USPQ 49, 50 (CCPA 1956). Here, the specification does not "inevitably" set forth all processed forms of high-density polyethylene. To the contrary, most "processed" forms of high-density polyethylene cannot be used in surgery at all (e.g., see Wikipedia, the Free Encyclopedia. High Density Polyethylene. Retrieved April 23, 2006, pages 1 and 2 showing various forms that are used in Tupperware, milk cartons, plastic bags, etc.; see also POREX Surgical Products Group. MEPOR Biomaterial. Retrieved April 23, 2006, pages 1-12, especially

page 2, column 2, "MEDPOR is a biocompatible porous polyethylene material" and page 8, column 2, "MEDPOR BARRIER .... is made of non-porous high-density polyethylene" showing that high-density polyethylene can be produced in both "porous" and "non-porous" forms; see also Ho, T. "Biopolymers in Otolaryngology" Baylor College of Medicine http://www.bcm.edu/oto/grand/3312005.htm, accessed on 4/23/06, pages 1-9, especially, page 4, middle paragraph showing that only "porous" high density polyethylene is used in surgery because it allows "soft tissue ingrowth" and perhaps "limited osseous integration"). In addition, Applicants admit that all processed forms cannot be used in surgery (e.g., see 8/22/06 Response, page 8, paragraph 1, "If the HDPE-containing article is intended to be implanted, it will be made in an anatomical shape and sterilized").

Furthermore, as mentioned above, the specification fails to disclose non-porous high-density polyethylene like MEPORE BARRIER. Whether such a non-porous material has been used in surgical application by is not material others (e.g., see 8/22/06 Response, page 8, last full paragraph) because it does not provide evidence that Applicants used such materials. The simple fact is that Applicants' specification does not disclose the use of MEDPORE BARRIER or any other non-porous high-density polyethylene. Furthermore, none of Applicants' declarations proclaim that MEDPORE BARRIER or any other form of non-porous high-density polyethylene was used. Applicants also admit that materials with small pores are inappropriate (e.g., see specification, paragraph 42, "materials with pores between one and fifty microns are susceptible to bacterial invasion, with little chance of an effective host immune response"). Finally, none of Applicants' declarations proclaim that other "processed" forms of high-density polyethylene like milk cartons, Tupperware, etc. were used either (i.e., Applicants' are not in possession of using

milk cartons in facial surgery). Therefore, Applicants' arguments are moot.

Accordingly, the New Matter rejection cited above is hereby maintained.

New Rejections

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1, 4, 7-11, 13, 22, 23, 25-29 and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 1, 22, 28, 29 and 31**, the term "size" is vague and indefinite because the word commutates the "overall dimension" of an object i.e., in the x, y and z dimension (e.g., see Compact Oxford English Dictionary. Size. Retrieved at http://www.askoxford.com/concise_oed/size_1?view=uk on October 11, 2006, page 1, "noun 1 the overall dimensions [i.e., x, y, z dimensions]") and, as a result, would not be measure in microns but, rather, microns cubed. Furthermore, even if, *assuming arguendo*, the "size" of a particle could be fairly interpreted to a suggest only one dimension consistent with Applicants' "micron" label then, alternatively, the Examiner contends that is not clear whether Applicants' are referring to the radius, diameter, or some other quantity in the specification. For example, if the particles are not spherical, what quantity is being measured? Applicants are requested to clarify and/or correct.

Therefore, claims 1, 22, 28, 29, 31 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 4, 7-11, 13, 22, 23, 25-29 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Independent claims 1, 22 and 31 claim particles with a size "greater than" 60 or 100 micrometers. However, there is no support for the upper range of this limitation in the specification. To the contrary, Applicants state, "Compositions of the present invention comprise particles having a size range of approximately 60 microns to approximately one millimeter are useful in methods for soft tissue augmentation" (e.g., see specification, paragraph 49). That is, the specification does not provide support for particles with sizes "greater than" one millimeter. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 4, 7-11, 22, 25-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Lum et al. (U.S. Patent No. 5,468,401) (Publication date is **November 21, 1995**) as evidenced by Applicants' specification (e.g., see paragraph 53).

For ***claims 1, 22 and 31***, Lum et al. (see entire document) discloses lubricating compositions (e.g., see abstract), which anticipates the claimed invention. For example, Lum et al. disclose biocompatible micronized high-density polyethylene particles having a size greater than one-hundred microns (e.g., see Lum et al., column 7, lines 36-44, "Typical materials which ... function as solid lubricants are high melting polymer resins; see also paragraph bridging columns 7 and 8, "Useful high melting polymer resins include ... high-density polyethylene (HDPE)"; see also column 17, paragraph 1, "Substantially uniform sized lubricant particles, having a mean particle size (i.e., diameter) within the range of 10 microns to 420 microns produced acceptable results"). In addition, Lum et al. disclose a physiological carrier such as PVP (e.g., see columns bridging columns 19 and 20, "Binder components that may effectively be used to adhere the component lubricant particles in the agglomeration process of the present invention include ... polyvinylpyrrolidone (PVP)"; see also column 19, lines 9 and 10 wherein K30, K60 and K90 are disclosed, "The binder may contain thickening agents, such as polyvinylpyrrolidone ... K-Series* e.g., K30 ... K60"). Lum et al. do not state that this

composition is injected into soft tissue. However, the Examiner has not afforded this limitation any patentable weight because it represents intended use language only. If the prior art structure is capable of performing the intended use, then it meets the claim. The Office does not have the facilities to make a comparison and the burden is on the applicants to establish any difference between the transducing elements of the art and the instant claims. Se *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). Furthermore, Lum et al. do not state that the HDPE or PVP is biocompatible. However, the Examiner contends that this is an inherent feature of the HDPE/PVP because a chemical composition and its properties are inseparable. If the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP § 2112.01. The Office does not have the facilities to make such a comparison and the burden is on the applicants to establish the difference. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.).

For ***claims 4 and 7***, Lum et al. teach, for example, polyvinylpyrrolidone (e.g., see columns bridging columns 19 and 20, "Binder components that may effectively be used to adhere the component lubricant particles in the agglomeration process of the present invention include ... polyvinylpyrrolidone (PVP)"; see also column 19, lines 9 and 10

wherein K30, K60 and K90 are disclosed, "The binder may contain thickening agents, such as polyvinylpyrrolidone ... K-Series* e.g., K30 ... K60").

For ***claims 8-11, 22, 25-27***, Lum et al. teaches the use of any commercially available "K-series" PVP and explicitly references K30, K60, etc. (e.g., see column 19, lines 9 and 10). Although Lum et al. do not explicitly state that they use K17, the Examiner contends that K-17 is inherently disclosed by the reference as evidenced by Applicants' specification. For example, Lum et al. state that any commercially available "K-series" PVP can be used (e.g., see column 18, lines 9 and 10) and Applicants' specification admits that K17 was commercially available before the time of filing (e.g., see specification, paragraph 53, "... most preferable is a composition of K17 [i.e., a "K-series" PVP]. PVP is commercially available from GAF Chemical Corp.").

For ***claims 28 and 29***, Lum et al. teach particle sizes greater than 100 microns (e.g., see column 17, paragraph 1, "Substantially uniform sized lubricant particles, having a mean particle size (i.e., diameter) within the range of 10 microns to 420 microns produced acceptable results").

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 4, 7-11, 13, 22, 23, 25-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bisson (FR 2785811) (of record) in view of Henderson et al. (U.S. Patent 4,828,827) (Published **May 9, 1989**) as evidenced by SigmaAldrich (SigmaAldridch, Reference: Polymer Properties. Retrieved at http://www.sigmaaldrich.com/img/assets/3900/Viscosity.pdf on October 13, 2006, page 1).

For ***claims 1, 4, 7 and 13***, Bisson teach all the limitations stated in the 35 U.S.C. 102(b) rejection above (incorporated in its entirety herein by reference), which anticipates and, as a result, renders obvious claims 1, 4, 7 and 13.

The prior art teaching of Bisson differ from the claimed invention as follows:

For ***claims 8-11, 22, 23, 25-29 and 31***, Bisson fail to disclose a specific K value for the PVP.

However, Henderson et al. teach the following limitations that are deficient in Bisson:

For ***claims 1, 4, 7, 13, 28 and 29***, the Examiner further argues that in the alternative that Bisson et al does not anticipate the claimed "size" limitation i.e., greater than 100 microns (which is not the case see 35 U.S.C. § 102 rejection above), then Bisson would nevertheless "render obvious" such a limitation obvious even if Applicants' purported "between" language applies (e.g., see 8/22/06 Response, page 5, last paragraph). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). In the present case, a person of skill in the art would expect a composition having a size slightly less than 100 microns (e.g., 99.9999999) to possess the same properties as a composition having a size slightly greater than 100 microns (e.g., 100.0000001). The change is simply negligible by any standard.

For ***claim 8-11, 23, 23, 25-29 and 31***, Henderson et al. (see entire document) teach the use of PVP to augment soft tissue including molecular weights from 10,000 to 700,000 (e.g., see Henderson et al., column 2, paragraph 1, "Polyvinyl pyrrolidone is commercially available as a high melting water soluble polymeric powder in viscosity ranges which correspond to number average molecular weights from 10,000 to 700,000"). In addition, Henderson et al. state that suitable concentration ranges for said

PVPs includes 5-40% (e.g., see Henderson et al., column 2, "... concentration range suitable for producing homogeneous soft gels suitable for use as a soft tissue filler implant is 5-40%, and preferably 10-20%, by weight of the solution"). Henderson et al. do not actually state explicitly state the K values, but the Examiner contends that 12-100, 12-50, 12-20 and 17 are inherently disclosed as evidenced by SigmaAldrich showing K values of 13-19 for 10,000 MW at 20% solution and 26-34 for 40,000 MW 20,000 solution (e.g., see SigmaAldrich, Table III, entries 1 and 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use the PVP gels as taught by Henderson et al. with the compositions disclosed by Bisson because Henderson et al. explicitly state that these gels are used in "soft tissue" replacement (e.g., see title and abstract, "An aqueous gel of cross-linked polyvinyl pyrrolidone is used to augment soft tissue in a mammal"), which is exactly the PVP compositions in Bison are used for (e.g., see Bisson, page 1, paragraph 1, "The present invention concerns compositions ... usable for implantation in a tissue, in particular ... 'soft tissue augmentation'"). Furthermore, one of ordinary skill in the art would have been motivated to use the compositions of Henderson et al. because Bisson states, "[t]he consistency of the gel should be as close as possible to that of the living tissue into which it is to be implanted" (e.g., see Bisson, page 5), which is exactly what Henderson et al. provides by providing for a facile adjustment of consistency (e.g., see column 2, lines 44-57, "As the concentration of PVP is increased from 5 to 40% by weight in the aqueous carrier, the gels become softer and less friable ... Therefore, it is possible to alter the consistency of the hydrogels by manipulating concentrations of

polymer or other additives") (emphasis added). In addition, the PVP gels set forth Henderson et al. has "a remarkable lack of tissue reaction" and is "long lasting" (e.g., see column 1, lines 35 and 36). Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because both Bisson and Henderson et al. teach the use of PVP for soft tissue augmentation. Furthermore Henderson et al. states that said PVP has "a remarkable lack of tissue reaction" and is "long lasting" (see above). Furthermore, the PVP composition disclosed by Henderson et al. can be easily sterilized and injected using a common syringe (e.g., see Henderson et al., column 2, lines 32-34, "After the irradiation treatment the gel is sterile and ready for use, for example, for injection under a wrinkle to plump up the skin") as required by Bisson (e.g., see Bisson translation, page 5, paragraph 3, "The consistency of the suspension agent will be adapted to the implantation procedure used, for example, to allow intradermal or subcutaneous injection").

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
October 14, 2006